

Clarification on HeiQ Data Requirements



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: July 6, 2020

SUBJECT: Clarifications Regarding the HeiQ Data Requirements Relative to the
Registration Review Data Call in for the Nanosilvers Case.

PC Code: 072599	Docket #: EPA-HQ-OPP-2009-1012, EPA-HQ-OPP-2011-0370
Decision No.: NA	Registration Number: 85249-1, 85249-2
Risk Assessment Type: Note to file	Case No.: 5042

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In 2011, EPA conditionally registered a liquid product containing nanosilver, HeiQ, for use as a material preservative in textiles. The conditional registration was based on the need for additional data to confirm the assumptions which EPA used in drafting the risk assessment which was associated with the conditional registration.

Further, EPA reviewed all of the silver and silver salts registrations for the first Registration Review cycle to determine if any of the silver products contained nanoparticles as the active ingredient. There were 5 products which had nanoparticles and these products along with the HeiQ registration were considered to be in the Nanosilvers Registration Review Case #5042. A

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Data Call In (DCI) was issued in August 2019 to support a registration review risk assessment. HeiQ received this DCI which included many of the data requirements which were part of HeiQ's conditional registration.

There were some data requirements that were required of HeiQ in the Nanosilver DCI which were not on the registration review DCI. The purpose of this memo is to discuss the discrepancies which are listed below:

Tier II Solubility – required as condition of registration

- a. Data are required on the Nanosilver DCI, but the study is called “Dissolution Kinetics” instead of Tier II solubility.
- b. HeiQ submitted a dissolution kinetics discussion in MRID 50534302 along with other characterization studies. The information submitted was not sufficient since it examines released ions instead of released particles.
- c. Data are still needed for HeiQ

Modified aquatic food chain transfer – conditional/”on hold” as condition of registration

- a. The Nanosilver DCI requires a bioaccumulation in fish study and that information could be used to characterize the potential for aquatic food chain transfer.
- b. Data could be waived at this time for HeiQ by citing the bioaccumulation in fish data.

Terrestrial plant toxicity, Tier 1 seedling emergence – conditional/”on hold” as condition of registration

- a. Most concerns for the current uses of HeiQ are for aquatic plants, with little expected exposure to terrestrial plants.
- b. Aquatic plant data are listed as required in the Nanosilver DCI.
- c. Data could be waived at this time for HeiQ based on potential low terrestrial exposure and the submission of aquatic plant data.

Sediment ecotoxicity studies:

Sediment toxicity – *Chironomas* - conditional/”on hold” as condition of registration

Sediment toxicity – *Hyalella* – required as condition of registration

Sediment toxicity – *Leptocheirus* - conditional/”on hold” as condition of registration

- a. At this time, there are no approved models available for evaluating exposure from AD uses to sediment organisms.
- b. Since there are no models to quantitatively assess risks to benthic organisms from AD uses and the data could only be used qualitatively, AD did not require these chronic sediment ecotoxicity studies in the Nanosilver DCI. In lieu of these data, ecotoxicity data from non-benthic aquatic organisms could be used as a proxy.

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- c. Data could be waived at this time for HeiQ. If adsorption data indicates that HeiQ adsorbs to sediment, risks to sediment organisms will be assumed to be similar to non-benthic aquatic invertebrates.